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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.           | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------------|------------------|
| 10/672,914   | 09/25/2003  | Brian B. Lentricchia | 2024738-7030290000<br>(11.02) | 9190             |
| 38732  | 7590        | 12/29/2005           | EXAMINER                      |                  |
| CYTYC CORPORATION<br>250 CAMPUS DRIVE<br>MARLBOROUGH, MA 01752 |             |                      | HINES, JANA A                 |                  |
|  |             |                      | ART UNIT                      | PAPER NUMBER     |
|  |             |                      | 1645                          |                  |

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/672,914

Applicant(s)

LENTRICHIA, BRIAN B.

Examiner

Ja-Na Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 December 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,8-13,21 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,6,7,14-20 and 22-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9/25/03, 11/6/03
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Species I, II and III in the reply filed on September 9, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 4-5, 8-13, 21 and 25 have been withdrawn from consideration. Claims 1-3, 6-7, 14-20 and 22-24 are under consideration in this office action.

### ***Information Disclosure Statement***

2. The information disclosure statement (IDS) submitted on September 25, 2003 and November 6, 2005 was in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Specification***

3. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The use of the trademark "PreservCyt Solution" on page 12, para. 3, along with other Trademarks throughout the specification have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 3, 7, 17 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claim 3 recites the limitation "the sensor." There is insufficient antecedent basis for this limitation in the claim.

b) Claim 7 recites the limitation "the target." There is insufficient antecedent basis for this limitation in the claim.

c) Claim 17 recites washing the sample prior to the determination step. The term is vague and indefinite since it is unclear how this is accomplished if the target molecule is not part of a cell. Thus the claim is unclear and appropriate clarification is needed to overcome the rejection.

d) Claim 19 recites the limitation "the first label" in the claim. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3, 6-7, 17, 19-20 and 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Bruchez et al., (US Patent 6,274,323).

The claims are drawn to a method for assaying a sample for the presence of a target molecule comprising: providing a liquid sample suspected of comprising the target molecule which is a cell surface molecule; contacting the sample with a filter, said filter comprising a sensor which is an antibody attached thereto, said sensor molecule capable of specifically binding to the target molecule, if present; passing the sample transversely through said filter using a pressure-controlling apparatus under conditions that allow the sensor molecule to bind to the target molecule; recovering the remaining liquid sample; and determining whether the target has bound to the sensor. The dependant claims are further drawn to the plurality of different sensors, the inclusion of a wash step, the use of a labeled antibody sensor, and a fluorophore labeling agent.

Bruchez et al., teach the use of semiconductor nanocrystals as detectable labels in assays which can detect multiple analytes (col. 1, lines 15-20). The instant methods teach a method of detecting one or more target analytes in a sample providing a specific binding molecule on a solid support, combining the sample with the specific binding molecule to allow the formation of the specific-binding molecule and analyte,

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further combining the complex with a nanocrystal conjugate and detecting the presence of the complex which indicates the presence of the one or more targets in the sample (col. 5-6, lines 55-10). The specific binding molecule can be an antibody which will bind to any antigen of interest including cell surface molecules (col.12, lines 20-25). The biological sample refers to a sample of isolated cells, tissue or fluid including plasma, serum, spinal fluid, semen, lymph fluid, external sections of skin, respiratory, intestinal, genitourinary tracts, tears, saliva, milk, blood cells, tumors, organs and in vitro cell culture constituents (col. 13, lines 60-68). The solid support can be any material such as membranes made of nitrocellulose, polymeric sheets or solid fibers which include those made of cellulose (col. 22, lines 52-68 and col. 25, lines 45-48). The specification defines filter to be any material to which a sensor can be attached and which does not adversely impact the sample (page 18, lines 1-6) thus, the solid support of the instant patent meets the limitations taught by the specification. The solid support can then be coated and immobilized with the antibody (col. 25, lines 53-60). Suitable apparatuses include the use of capillaries , hollow fibers, needles, pins and the like (col. 22, lines 53-55) all of which are capable of controlling the pressure of the liquid sample by limiting the rate and amount of sample taken in. Thus, Bruchez et al., meet the instant limitations. Thereafter, the support bound component is then contacted with the biological sample suspected of containing ligand moieties such as antigens towards the immobilized antibodies (col. 26, lines 7-14). Then, after washing, a secondary binder moiety detectable labeled with the semiconductor nanocrystals can bind and thereby be detected (col. 26, lines 15-20). Many of the examples teach the use of flow cytometry

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along with detection using flow cytometers (see examples 3, 4, and 8). Flow cytometers are known to place the remaining sample in separate tubes of culture wells, thus allowing for the remaining liquid sample to be recovered. Therefore, Bruchez et al., teach a method for assaying a sample for the presence of a target molecule just as required by the claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bruchez et al., in view of Hurley et al., (US Patent 5,256,571).

The claim is drawn to a method of assaying a sample for the presence of a target molecule wherein the sample comprises a water-soluble alcohol in an amount effective to preserve the sterility of the solution toward at least one contaminant.

Bruchez et al., has been discussed above, however it does not disclose a sample comprises a water-soluble alcohol in an amount effective to preserve the sterility of the solution toward at least one contaminant.

Hurley et al., teach an alcohol buffer solution for preservation prior to staining or other forms of analysis (col. 2, lines 1-5). Because it is necessary to get a sample at a different time then when analysis is being performed, it is desirable to preserve the cell

sample, prevent bacterial growth which may occur because of extended preservation and prevent further interference with the sample (col.1, lines 50-68). The solution also effectively destroys microbial pathogens in a sample and inhibits retroviral activity (col.3, lines 9-11) which preserves the sterility of the sample just as required by the claims. The preferred alcohol is methanol, which is a water-soluble alcohol (col.3, lines 27-30). In practicing the method, a cell sample is obtained from a patient or other cell source and then the sample is placed in the preservative solution (col. 4, lines 23-33).

Therefore, it would have been prima facie obvious at the time of applicants invention to modify the method of assaying a sample for the presence of a target molecule as taught by Bruchez et al., to further include using a water-soluble alcohol preserving solution as taught by Hurley et al. No more than routine skill would have been required to incorporate the water-soluble alcohol into the sample, since the prior art teaches the beneficial effects of inhibiting bacterial growth which may affect the sterility of the sample due to preservation. Furthermore, one of ordinary skill in the art would have a reasonable expectation of success, since the prior art teaches that the solution can be used with a wide variety of cell types and allows the cell samples to maintain their integrity and be further analyzed without any interference from the storage and preservation.

#### ***Prior Art***

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Root et al., (US Patent 4,200,690) Root et al., teach an

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immunoassay with microporous membrane filter having immobilized antibody capable of detecting the target antigen. Stanton et al. (US Patent 4,803,170) teach a test device for detecting analyte molecules in a fluid sample. Schutt (US Patent 4,357,311) teach immunoassay procedures for the quantitative and qualitative determination of various substances in body fluids such as blood, urine and saliva using filter membranes are coated with antibody.

### ***Conclusion***


8. No claims allowed.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.  
  
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines 

December 5, 2005

  
**ROBERT A. ZEMAN,**  
**PATENT EXAMINER**